cunesoft
compliance delivered

# User Manual –

# Cunesoft General Administration

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# USER MANUAL – Cunesoft General Administrations

The Cunesoft online software system is provided as modular solution. Each module (i.e. cune-SOP, cune-RDMS, cune-eCTD, cune-Track, cune-Portal etc.) can be used as standalone solution or in combination with one or multiple other Cunesoft modules.

General Administration is a function available to General Administrators. The available configuration options are described within this document. They consist of four major areas:

- E-Mail Template Management
- Workflow Management
- User Management
- Group Management

NOTE: Each Cunesoft module does have an additional, module specific administration site, which is only accessible if the Cunesoft module is licensed and enabled.

## 1. E-Mail Template Management

The system comes with an integrated automated E-mailing function. E-mails are being sent upon begin and/or end of specific workflow tasks. The system comes pre-configured with standard texts. The E_mail template management function allows personalizing the text content of each E-mail.

### 1.1 Edit an E-mail Template

To edit an E-mail template in your system perform the following steps as General Administrator:

1. Enter the E-Mail Template Management
2. Click on the type of E-mail template you want to edit.
3. Enter your changes.
4. Click on save.

Result: The new version of the E-Mail Template will be saved.

Attention: Please be careful with changing links within the E-mail, since these links are specific to each E-mail.

### 1.2 Shortcodes Overview

The already pre-defined E-Mail Templates include specific shortcodes. The shortcodes are placeholders for dynamic content, which are for example related to a user name, to a specific document or to a date. The easiest way to work with the short codes is to copy and paste them if you are changing the E-Mail Template.

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The cune-System has several built-in shortcodes:

{DOCTITLE} – Generates the name of a shared document within a Document Share Notification.

{DOCUMENTDOWNLOAD} – Generates a link to a document which can be used to download the document.

{EFFECTIVEDATE} – Generates the date until a SOP was made effective.

{FORMNUMBER} – Generates the number of a FORM.

{FORMTITLE} – Generates the name of a FORM.

{INSTANCEURL} – Generates a link within a Document Share Notification which is linked to the shared document.

{LOGINURL} – Generates a link with log-in information for new users which can be used to access the system.

{PASSWORD} – Generates a Password for new users automatically, the user can change the Password after the first login.

{REASON} – Generates the reason which a user stated within a rejection of a document.

{REJECTUSERNAME} – Generates the name of the user who rejected a document.

{SHAREDVIAUSER} – Generates the name of the user who has shared a document.

{SOPTITLE} – Generates the SOP-Title of a document automatically.

{SOPNUMBER} – Generates a SOP-Number of a document automatically.

{TASKLINK} – Generates a link to a signature task.

{TITLE} – Generates the title of the Email Header.

{USERNAME}- Generates for each user his username, which can be used for the log-in into the system.

{YEAR} – Generates the current year information.

# 2. Workflow Management

This is a detailed view of all workflow elements with the following information:

- Type
- Title
- Status
- Current task status
- Current task title
- Current task assigned

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# 3. User Management

The system supports a role based user management. A user can have multiple roles. Depending on the assigned roles, certain functions, views are available for the user.

## 3.1 Create User

To add a new user to the system the following steps should be performed

1. Enter the User Management
2. Click the Create User button (if you do not see the button, click on the arrow on the right side of the screen)
3. Type in an E-Mail address, first name, last name of the user you would like to create.
4. Click on *Create User* to complete the process.

Result: An E-mail will be sent to the new user. The E-mail includes an invite to join the system, a link to the logon website, user credentials and a system generated password. The new user will have only view permissions. Should the user be part of additional roles, then these need to be assigned by the General Administrator.

## 3.2 Lock User

In case a user is not required to use the system anymore (due to leaving the company, changing roles etc.) then this user should be locked. Via locking the user, the audit trail of the user remains within the system, but the user cannot access the system anymore and perform any further actions. From a regulatory compliance perspective and in order to maintain a complete audit trail, it is recommended to lock a user instead of deleting a user.

To lock a user in your system perform the following steps as General Administrator:

1. Enter the User Management
2. Click the *Options* button on the user you would like to lock
3. Select *Lock* from the dropdown list.
   The user won't be able to log in into the system anymore.
   All user data are stored in the database for reasons of complaints.

Result: The user will be notified via E-mail about the performed system lock. The locked user cannot access the system anymore, unless an unlock action has been performed by a General Adminstrator.

## 3.3 Unlock User

To unlock a user within the system perform the following steps as General Administrator:

1. Enter the User Management
2. Click the *Options* button on the user you would like to unlock
3. Select *Unlock* from the dropdown list.

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Result: The user will be notified via E-mail about the performed system unlock. The user will be able to log in into the system again.

### 3.4 Reset Password

To reset a user password within the system the following steps should be performed as General Administrator:

1. Enter the User Management
2. Click the *Options* button on the user you would like to reset the password.
3. Select *Reset Password* from the dropdown list.

   Result: The user will receive an e-mail with a new random generated password. The old password is no longer valid anymore. The user is then recommended to set an individual password.

## 4. Group Management

The system supports a role based user management. Depending on the user group the user has been assigned too, certain user group specific actions can be performed by the user. Also views and library access capabilities are different for different user groups. The definitions for each user group is explained below.

### 4.1 User Groups

#### 4.1.1 Quality Assurance

Is able to:

- Approve documents
- Reject documents
- Conduct a review

#### 4.1.2 Global Administrator SOP

Is able to:

- Edit e-mail templates
- Create users
- Lock users
- Unlock users
- Rest user password
- Add users to groups
- Remove users from groups

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#### 4.1.3 SOP Administrator

Is able to:

- Upload a SOP template file
- Enable training
- Enable additional approvers in the approval workflow
- Set SOP number prefix
- Set sop number postfix

#### 4.1.4 SOP Author

Is able to:

- Create SOPs
- Upload SOPs
- Read SOPs
- Edit SOPs
- Delete SOPs
- Start review workflows
- Start approval workflows

#### 4.1.5 SOP Reader

Is able to:

- Read SOPs

#### 4.1.6 Training Manager

Is able to:

- Create trainings

#### 4.1.7 Training User

Is able to:

- Conduct a training

#### 4.1.8 Sharing User (internal user)

Is able to:

- Share documents

#### 4.1.9 Sharing Portal External User

Is able to:

- Access documents which have been shared by internal users

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### 4.2 Add User to Group

To add a user to a specific group within the system the following steps should be performed as General Administrator:

1. Enter the Group Management
2. Click the *Options* button on the group you would like to add a user.
3. Select *Add User* from the dropdown list.

Result: The user will immediately have all permissions as defined for this group. The user name appears within the group member list.

### 4.3 Remove User from Group

To remove a user from a specific group within the system the following steps should be performed as General Administrator:

1. Enter the Group Management
2. Click the *Options* button on the group you would like to remove a user.
3. Select *Remove User* from the dropdown list.

Result: The user will immediately not have the user group permissions anymore. The user name disappears within the group member list.

## 5. Additional Descriptions

### 5.1 Data Storage Security

All data is stored with encryption within a customer specific unique database. For further details please refer to the Cunesoft SSLA.

### 5.2 Automatic Backup

Cunesoft automatically stores a backup of the system in a secondary datacenter. For further details please refer to the Cunesoft SSLA.

### 5.3 Automatic Time Out (Logout)

If a user is ineffective within the system for more than 20 minutes, the system automatically log’s off a user.

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